FDA-iRISK
food safety modeling tool

From the U.S. Food and Drug Administration

A Closer Look at FDA-iRISK

FDA-iRISK, an interactive, Web-based system developed by the U.S. Food and Drug Administration, is available to the public, to enable users to relatively rapidly conduct fully quantitative, fully probabilistic risk assessments of food-safety hazards. It can be used to systematically and efficiently compare and rank (1) estimated risks from multiple microbial or chemical food-safety hazards and (2) estimated effectiveness of various changes in specific steps of a food's farm-to-table pathway, for preventing or reducing illness from the hazards. FDA-iRISK generates results as public-health metrics, for example, to enable risk managers to compare the public-health impact of risks and interventions.

This fact sheet provides a general sense of the inputs required of users and the outputs produced by FDA-iRISK. (Comprehensive training is available; to find opportunities, periodically check http://www.foodrisk.org.) FDA-iRISK is not intended to replace the kinds of risk assessments that usually address only a single food-hazard combination at much greater length; rather, it is designed to allow comprehensive, more rapid risk ranking of many food-hazard combinations and potential solutions.

Broad Picture of FDA-iRISK

The figure on the reverse side of this fact sheet gives an overview of the FDA-iRISK model structure; i.e., inputs and outputs. Users enter data to build scenarios that reflect the food-hazard pair and situation of interest, with support from built-in, standard data-entry templates. Analytica Decision Engine software then uses built-in equations to perform Monte Carlo simulations in pre-structured models, to generate results as estimated public-health outcomes (e.g., DALYs).

The scenarios that users build can include any or all processes in the chain for production, processing, distribution, sale, and consumption of a specific food, via pre-loaded process types. Changes in the hazard prevalence and concentration can be addressed at any step of the chain, including changes resulting from interventions applied at those steps. Users can vary their data input in their scenarios, to estimate the differences that would result in public-health outcome; for example, by focusing on specific subpopulations or varying hazard concentration at different steps of the food chain.

The User's Role

Users enter data for seven elements, in templates that inform pre-structured models. The program uses mathematical logic and Monte Carlo simulation to integrate the data and generate results. The seven elements are:

- the **food**, **hazard**, and **population** of interest;
- models for **process** (i.e., processes through which the hazard prevalence and concentration change at various steps in the food chain), **consumption** patterns, and **dose-response**;
- the **DALY template** (reflects, e.g., the severity of the health outcomes in the population under consideration and the fraction that each outcome comprises. These data, once entered in the template by the user, are saved by FDA-iRISK, allowing subsequent users to adopt the completed template as is or to build on it, after which FDA-iRISK would again save the augmented template for future users).

Users need to have experience or considerable understanding of how risk assessments are actually conducted. For example, to populate the dose-response model with their data, users must know which of the model options offered by FDA-iRISK (e.g., Beta-Poisson vs. exponential) will best accomplish their objectives.

Indirect Users Are a Key Audience

FDA-iRISK is intended for direct use by risk assessors, but risk managers are among the most important indirect users. For example, they are most likely to be aware of the public-health questions that can be addressed by FDA-iRISK and to initiate requests, and to put to practical use the public-health metrics generated by the program, in forming decisions about food-safety policy and other issues. The relatively rapid results produced by FDA-iRISK are beneficial to risk managers and other food-safety decision-makers.

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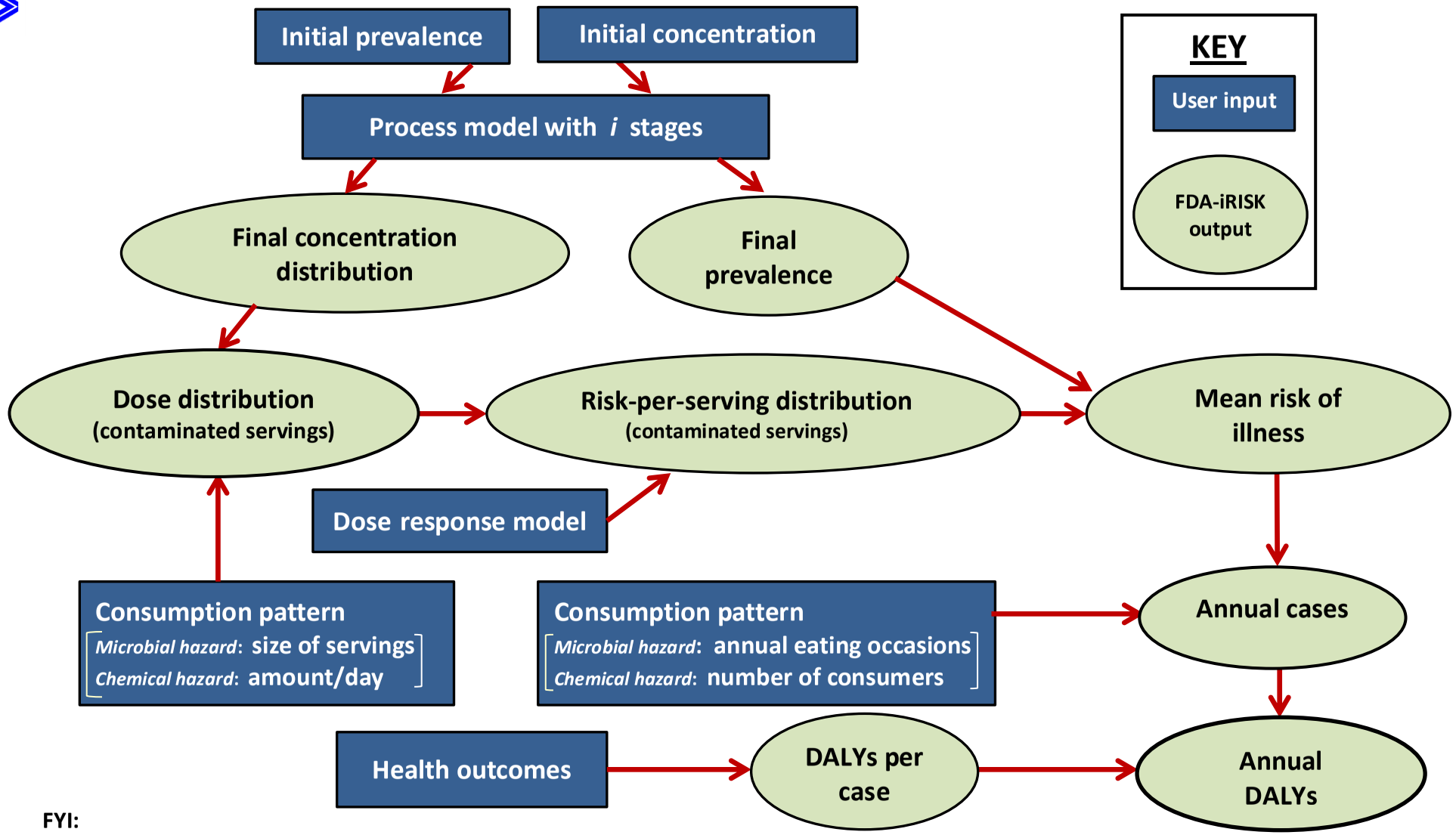

FYI:

Process model – FDA-iRISK lists process types through which the hazard can change at various steps in food chain (e.g., by growth or inactivation, or by food evaporation, dilution, partitioning, etc.). User chooses a process type for each step in the process model and populates the model with data.

Dose-response model –FDA-iRISK offers choices of pre-structured dose-response models. User selects one and populates it with data. Equations are embedded; FDA-iRISK does the calculations.

Health outcomes – For each hazard, FDA-iRISK provides a template for user to enter data on severity and duration of potential health outcomes, including relative frequency of each outcome (i.e., among all outcomes from the hazard, the fraction that each outcome comprises). This template and the data entered in it are the means by which FDA-iRISK incorporates severity of illness (burden of illness) in public-health metrics.